

AMENDMENTS

In the Claims:

1-2. (Cancelled).

3. (Currently Amended) A device for collecting a fluid specimen, comprising:

a container configured to receive the fluid specimen;

a plunger movably positioned within the container, wherein the plunger moves from a first position at an upper region of the container to a second position below the first position;

a fluid segregation chamber configured to receive a portion of the fluid specimen from the container, wherein fluid in the segregation chamber is segregated from fluid in the container;

a fluid flow lumen that provides a passageway for at least a portion of the fluid specimen to flow into the fluid segregation chamber, wherein a first end of the passageway has a first opening that opens into the fluid segregation chamber and a second end of the passageway has a second opening configured to receive at least a portion of the fluid specimen; and

a seal member that covers the first opening or the second opening, wherein the seal member prevents fluid from entering the fluid segregation chamber until the seal member is broken;

wherein the plunger is configured to move from the first position toward the second position upon insertion of a test element to effect breaking of the seal member and further causing at least a portion of the fluid specimen to flow through the second opening into the fluid flow lumen and out of the first opening into the fluid segregation chamber; and

The device of claim 1, further comprising

a slot extending through the cap and communicating with the fluid segregation chamber.

4. (Currently Amended). The device of claim 32, further comprising wherein the cap is coupled to the container, and a plunger housing that extends downwardly from the cap into the container, wherein the plunger housing comprises sidewalls and a bottom wall.

5. (Previously Presented). The device of claim 4, further comprising a reservoir chamber positioned in a lower region of the plunger housing, and wherein at least one fluid entry port is located in the side wall of the plunger housing so as to communicate with the reservoir chamber, the fluid entry port providing a pathway through which at least a portion of the fluid specimen flows into the reservoir chamber from the container.

6. (Currently Amended). The device of claim 5, wherein the second opening of the fluid flow lumen opens into the reservoir chamber, and wherein at least a portion of the plunger blocks fluid from flowing into the fluid entry port when the plunger moves from the first position toward the ~~second position~~ second position such that fluid in the reservoir chamber flows into the fluid flow lumen as the plunger moves toward the second position.

7. (Currently Amended) ~~The device of claim 1;~~ A device for collecting a fluid specimen, comprising:
a container configured to receive the fluid specimen;
a plunger movably positioned within the container, wherein the plunger moves from a first position at an upper region of the container to a second position below the first position;
a fluid segregation chamber configured to receive a portion of the fluid specimen from the container, wherein fluid in the segregation chamber is segregated from fluid in the container;
a fluid flow lumen that provides a passageway for at least a portion of the fluid specimen to flow into the fluid segregation chamber, wherein a first end of the passageway has a first opening that opens into the fluid segregation chamber and a second end of the passageway has a second opening configured to receive at least a portion of the fluid specimen;
wherein the fluid flow lumen is located within the plunger; and
a seal member that covers the first opening or the second opening, wherein the seal member prevents fluid from entering the fluid segregation chamber until the seal member is broken;
wherein the plunger is configured to move from the first position toward the second position upon insertion of a test element to effect breaking of the seal member and further causing at least a

portion of the fluid specimen to flow through the second opening into the fluid flow lumen and out of the first opening into the fluid segregation chamber.

8. (Currently Amended) ~~The device of claim 4;~~ A device for collecting a fluid specimen, comprising:

a container configured to receive the fluid specimen;

a plunger movably positioned within the container, wherein the plunger moves from a first position at an upper region of the container to a second position below the first position;

a fluid segregation chamber configured to receive a portion of the fluid specimen from the container, wherein fluid in the segregation chamber is segregated from fluid in the container;

a fluid flow lumen that provides a passageway for at least a portion of the fluid specimen to flow into the fluid segregation chamber, wherein a first end of the passageway has a first opening that opens into the fluid segregation chamber and a second end of the passageway has a second opening configured to receive at least a portion of the fluid specimen;

a seal member that covers the first opening or the second opening, wherein the seal member prevents fluid from entering the fluid segregation chamber until the seal member is broken;

wherein the plunger is configured to move from the first position toward the second position upon insertion of a test element to effect breaking of the seal member and further causing at least a portion of the fluid specimen to flow through the second opening into the fluid flow lumen and out of the first opening into the fluid segregation chamber;

a cap that couples to the container; and

a plunger housing that extends downwardly from the cap into the container, wherein the plunger housing comprises sidewalls and a bottom wall;

wherein the plunger housing is removably attached to the cap.

9. (Currently Amended) A method of analyzing a fluid specimen, comprising:

providing the device of claim 3; ~~providing a container that contains the fluid specimen, the container including a fluid segregation chamber that can segregate at least a first portion of the fluid specimen from a second portion of the fluid specimen, wherein a fluid flow lumen provides a fluid~~

passageway for a portion of the fluid specimen to flow from the container into the fluid segregation chamber, the fluid flow lumen having a seal that prevents fluid from flowing into the fluid flow lumen; and

inserting a test element into the container so that the seal is punctured and the test element depresses a plunger to cause at least a portion of fluid in the container to flow into the fluid flow lumen and into the fluid segregation chamber, wherein at least a portion of the test element moves into the fluid segregation chamber in contact with the portion of the fluid specimen in the fluid segregation chamber.

10. (Currently Amended) The method of claim 9, ~~additionally comprising coupling a cap onto the container,~~ wherein the cap is coupled to a plunger housing that defines a plunger shaft in which the plunger is movably positioned.

11. (Original) The method of claim 10, wherein at least a portion of the fluid specimen flows into a reservoir chamber in a bottom region of the plunger housing when the cap is coupled to the container, and wherein the plunger decreases the volume of the reservoir chamber as the plunger is depressed to thereby force the portion of the fluid specimen in the reservoir chamber to flow into the fluid flow lumen.

12. (Original) The method of claim 11, wherein the portion of the fluid specimen flows into the reservoir chamber through at least one fluid entry port in the plunger housing, and wherein the plunger blocks the portion of the fluid specimen from flowing out of the reservoir chamber through the fluid entry port as the plunger is depressed.

13. (Currently Amended) The method of claim ~~10~~9, wherein inserting the test element into the container comprises inserting the test element through the slot in the cap.

14. (Currently Amended) A device for collecting a fluid specimen, comprising:

a container comprising a main chamber that is configured to receive thea fluid specimen;
a fluid segregation chamber coupled to the container for segregating at least a portion of the fluid specimen from the main chamber;

a fluid flow lumen that provides a passageway for fluid to flow from the main chamber into the fluid segregation chamber, the fluid flow lumen comprising an upper opening that provides access to the segregation chamber;

wherein the fluid flow lumen is positioned inside the plunger;

a seal member configured to cover the upper opening of the fluid flow lumen to prevent fluid from flowing through the upper opening to the segregation chamber; and

a plunger coupled to the container, wherein the plunger is configured to move in a downward direction to force at least a portion of the fluid specimen to flow into the fluid flow lumen toward the fluid segregation chamber, wherein the seal member prevents fluid from moving into the fluid segregation chamber until the seal is broken.

15. (Previously Presented) The device of claim 14, further comprising a cap coupled to the container, wherein the cap includes a plunger housing that extends downwardly into the container when the cap is coupled to the container.

16. (Currently Amended) The device of claim 1544, wherein a lower region of the plunger housing forms a reservoir chamber, and wherein the fluid specimen in the main chamber flows into the reservoir chamber through a fluid entry port in the plunger housing when the cap is coupled to the container.

17. (Original) The device of claim 16, wherein the fluid flow lumen has a lower opening that opens into the reservoir chamber and wherein the plunger blocks fluid in the reservoir chamber from flowing through the fluid entry port as the plunger moves downward, and wherein, as the plunger moves downward, the plunger displaces the fluid specimen in the reservoir chamber to cause the fluid in the reservoir chamber to flow into the fluid flow lumen toward the segregation chamber.

18. (Previously Presented) The device of claim 14, wherein the container is configured to receive a test element.

19-20. (Cancelled).

21. (Currently Amended) The device of claim 3 wherein the slot is configured to be sized to receive the test element ~~wherein~~such that at least a portion of the test element is located in the fluid segregation chamber as the test element pushes the plunger from the first position toward the second position.

22. (Currently Amended) The device of claim ~~4~~3 further comprising a plunger shaft located within the plunger housing.

23. (Currently Amended) The device of claim 15, wherein the plunger housing further comprises a shaft, wherein the plunger is configured to be translated through the shaft.

24. (New) The device of claim 3, further comprising the test element, wherein the test element is configured to move the plunger from the first position toward the second position.

25. (New) A method of analyzing a fluid specimen, comprising:

providing the device of claim 7; and

inserting the test element into the container so that the seal is punctured and the test element depresses a plunger to cause at least a portion of fluid in the container to flow into the fluid flow lumen and into the fluid segregation chamber, wherein at least a portion of the test element moves into the fluid segregation chamber in contact with the portion of the fluid specimen in the fluid segregation chamber.

26. (New) The method of claim 25, wherein the device further comprises a cap coupled to a plunger housing that defines a plunger shaft in which the plunger is movably positioned.

27. (New) The method of claim 26, wherein at least a portion of the fluid specimen flows into a reservoir chamber in a bottom region of the plunger housing when the cap is coupled to the container, and wherein the plunger decreases the volume of the reservoir chamber as the plunger is depressed to thereby force the portion of the fluid specimen in the reservoir chamber to flow into the fluid flow lumen.

28. (New) The method of claim 27, wherein the portion of the fluid specimen flows into the reservoir chamber through at least one fluid entry port in the plunger housing, and wherein the plunger blocks the portion of the fluid specimen from flowing out of the reservoir chamber through the fluid entry port as the plunger is depressed.

29. (New) The method of claim 25, wherein inserting the test element into the container comprises inserting the test element through a slot in the cap.

30. (New) A device for collecting a fluid specimen, comprising:

- a container configured to receive the fluid specimen;

- a plunger movably positioned within the container, wherein the plunger moves from a first position at an upper region of the container to a second position below the first position;

- a fluid segregation chamber configured to receive a portion of the fluid specimen from the container, wherein fluid in the segregation chamber is segregated from fluid in the container;

- a fluid flow lumen that provides a passageway for at least a portion of the fluid specimen to flow into the fluid segregation chamber, wherein a first end of the passageway has a first opening that opens into the fluid segregation chamber and a second end of the passageway has a second opening configured to receive at least a portion of the fluid specimen;

a seal member that covers the first opening or the second opening, wherein the seal member prevents fluid from entering the fluid segregation chamber until the seal member is broken; and

a test element configured to move the plunger from the first position toward the second position to effect breaking of the seal member and further causing at least a portion of the fluid specimen to flow through the second opening into the fluid flow lumen and out of the first opening into the fluid segregation chamber.

31. (New) A method of analyzing a fluid specimen, comprising:

providing the device of claim 30; and

inserting the test element into the container so that the seal is punctured and the test element depresses a plunger to cause at least a portion of fluid in the container to flow into the fluid flow lumen and into the fluid segregation chamber, wherein at least a portion of the test element moves into the fluid segregation chamber in contact with the portion of the fluid specimen in the fluid segregation chamber.

32. (New) The method of claim 31, wherein the device further comprises a cap coupled to a plunger housing that defines a plunger shaft in which the plunger is movably positioned.

33. (New) The method of claim 32, wherein at least a portion of the fluid specimen flows into a reservoir chamber in a bottom region of the plunger housing when the cap is coupled to the container, and wherein the plunger decreases the volume of the reservoir chamber as the plunger is depressed to thereby force the portion of the fluid specimen in the reservoir chamber to flow into the fluid flow lumen.

34. (New) The method of claim 33, wherein the portion of the fluid specimen flows into the reservoir chamber through at least one fluid entry port in the plunger housing, and wherein the plunger blocks the portion of the fluid specimen from flowing out of the reservoir chamber through the fluid entry port as the plunger is depressed.

35. (New) The method of claim 31, wherein inserting the test element into the container comprises inserting the test element through a slot in the cap.